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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/509,950

12/30/2004

Rainer Hipfel

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/509,950 | Applicant(s) HIPFEL ET AL. | |
| | Examiner Olga N. Chernyshev | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 17, 2008 has been entered.

Response to Amendment

2. Claims 13 and 18-20 have been amended, claims 14-17 and 30-31 have been cancelled as requested in the amendment filed on February 29, 2008. Following the amendment, claims 11-13 and 18- 26 are pending in the instant application.

3. Claims 11, 12 and 21-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper filed on June 16, 2006.

4. Claims 13 and 18-20 are under examination in the instant office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step that leads to the diagnosis of Alzheimer's disease. Applicant is advised that claims 13 and 18, as currently presented, do not recite the essential conclusive step of what stands for the diagnosis of Alzheimer's disease, such as higher ratio level as compared to control corresponds to diagnosis of AD, for example.

8. Further, it is suggested that claims 13 and 18 include the limitation "frontal cortex to temporal cortex and/or to hippocampus" to particularly delineate as what ratio is intended by the claims consistent with the data presented in the instant specification.

9. Claim 19 recites the limitation "alteration" in claim 13. There is insufficient antecedent basis for this limitation in the claim. Also, the claim encompasses any alteration (higher and lower levels of ratio values) as diagnostic for AD; however, the specification teaches only the higher levels being discovered as diagnostic for AD. Amendment to the claim to specifically point out that increased ratio levels indicate the diagnosis would obviate this ground of rejection.

10. Claim 20 is vague and ambiguous in section (i) and (ii), which appear to recite that any variation of the detected level is indicative of Alzheimer's disease. Applicant is advised to rewrite this section of the claim to better express the claimed subject matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by US

Publication No. 2003/0186249, published October 02, 2003, filed April 01, 2002.

Claim 20 is directed to a kit for diagnosing Alzheimer's disease comprising reagents that selectively detect a transcriptional product of the gene coding for polypeptide hTARPP of SEQ ID NO: 1 and instructions how to use the kit.

The US Publication No. 2003/0186249 document discloses polypeptide and polynucleotide sequences, "human TARPP genes", which have 100% structural similarity to the instant claimed molecules, see sequence alignment attached to the office action of June 25, 2007. Thus the product(s) of the instant claimed kit are fully disclosed in the '249 document.

The Federal Circuit in decision of *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) stated that adding new printed matter to a known product cannot make the product patentable.

Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even though the content of the instructions differed.). The court said, "If we were to adopt *Ngai*'s position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product". See also *In re Gulack*, 703 F.2d 1381,

1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").

See MPEP 2112.01, PRODUCT CLAIMS – NONFUNCTIONAL PRINTED MATTER DOES NOT DISTINGUISH CLAIMED PRODUCT FROM OTHERWISE IDENTICAL PRIOR ART PRODUCT.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 2, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649